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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,593	08/15/2001	Charles Boone	23572-501	1658

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 01/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/930,593	BOONE, CHARLES	
	<b>Examiner</b>	<b>Art Unit</b>	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,6-10 and 79-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 6-10 and 79-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action is a reply to the Paper filed 27 October 2004 in reply to the Non-Final Office Action mailed 24 February 2004. Claims 1, 6-10 and 73-82 were considered in the 24 February Office Action. Claims 1 and 7 were amended, claims 73-78 were canceled and claim 83 was added in the 27 October Paper. Claims 1, 6-10 and 79-83 are presently pending and under consideration.

#### ***Response to Amendment***

Rejection and objection to claims 73-78 is rendered moot by cancellation of the claims.

#### **Claim Objections**

Objection to claim 1 as containing informalities is withdrawn in view of the amendment.

#### **Claim Rejections - 35 USC § 112**

Claims 1, 6-10 and 79-82 stand rejected and newly added claim 83 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record and herein below in the response to arguments.

#### **Claim Rejections - 35 USC § 102**

Rejection of claims 1, 6, 7, 10, 73, 79 and 81 under 35 U.S.C. 102(e) as being anticipated by Dawson *et al.* (filed 10 December 1999) US 6,232,074 is withdrawn in view of the amendment of the base claim to require that the haploid strains in the output array have the same

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haploid mating type. This property would not be inherent to the array of Dawson *et al.* and the art does not provide the teaching or motivation to modify the array of Dawson *et al.* such that the strains of the output array have the same haploid mating type.

### ***Response to Arguments***

#### **Claim Rejections - 35 USC § 112**

Claims 1, 6-10 and 79-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

In response to the *prima facie* case and arguments of record, Applicant has amended the claims to recite that the mutation comprised by the input yeast strains is a deletion mutation. Applicant urges that, because deletion mutants of *Saccharomyces cerevisiae* and *Schizosaccharomyces pombe* were known to skilled artisans at the time of filing, the full scope of the claimed invention is adequately described. Applicant further argues that the disclosure in the application of an output array resulting from 8 different strains of yeast carrying a genetic alteration linked to a dominant drug resistant marker with an array of close to 5,000 deletion strains from *S. cerevisiae* provides a representative number of species of the claimed invention.

These arguments have been fully considered but are not deemed persuasive. As stated on page 5-6 of the Office Action mailed 18 June 2003, in the first full paragraph on page 2 of the specification, Applicant provides, “[the] arrays and the methods of analyzing such arrays of the present invention therefore fulfill a need in the art by providing simple and efficient methods for large-scale, high throughput analysis of genetic and protein-protein interactions.” As the utility of the claimed invention arises from the genetic and protein-protein interactions that can be

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identified therewith, a description of the claimed output arrays must include a description of said genetic and protein-protein interactions or at least the phenotypic characteristics of the double mutant strains of the claimed array. However, the specification is silent with regard to the phenotypic characteristics of any high-density output array other than those of the disclosed species in the specification.

The teachings of the specification are predominantly directed to the description of input arrays and methods of making output arrays. However, these teachings do not adequately describe the claimed output arrays made according to the methods because the relevant identifying characteristics of the output arrays (i.e., the phenotypes of the double mutant strains) are unpredictable. Clearly this is the case because the purpose of the claimed output arrays is to identify interactions that could not be predicted by one in possession of only the component input arrays. Thus, defining output arrays merely as the mating product of any two arrays of mutant yeast, even if the input arrays themselves are adequately described, is not in compliance with the description requirement.

The species set forth in the specification are not representative of any species not yet described because there is no basis by which the skilled artisan can extrapolate from the species described such that the relevant identifying characteristics of other species is known. Applicant has described a stochastic method with the purpose of identifying unpredictable interactions between yeast genes, yet asserts that the mating product of all possible combinations of deletion mutations is fully described by the mutations in the input strains. If this were the case, there would be no reason to practice the method because the phenotypic characteristics of each of the strains in the output array would already be known to the skilled artisan. For reasons of record

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and herein above, the skilled artisan would not, in fact, be able to envision the relevant characteristics of any species within the claimed output array other than those actually described in the specification. Therefore, the claimed invention fails to meet the written description requirement of 35 USC §112, first paragraph.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M. Sullivan, Ph.D.

Examiner

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DAVID G. SULLIVAN  
PRIMARY EXAMINER